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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,557	04/01/2004	Ronald M. Jones	52325-8019.US00	1236

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,557	JONES, RONALD M.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *15-22,31 and 34-37* is/are allowed.

6)☒ Claim(s) *1,4-14,23-30,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/29/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 4-14, 23-24, 26, 29-30 and 32-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8, 10, 13-16, 20-21, 24 and 26-28 of U.S. Patent No. 6,881,581. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite an assay device and method for measuring serum cholesterol associated with high density lipoproteins (HDL) in a blood fluid sample also containing lipoproteins other than HDL such as low density lipoprotein (LDL) and very low density lipoprotein (VLDL) comprising a sample distribution matrix effective to distribute a blood fluid sample from a sample application region to one or more sample collection regions, a HDL test pad in which HDL concentration can be assayed spaced apart from the sample distribution matrix, a reagent pad containing a reagent to selectively bind and remove non-HDLs from the sample, wherein the HDL test pad and reagent pad are joined together or attached to one another, and a mounting means that is effective to maintain the device in a sample distribution position, wherein the HDL test pad and reagent pad are spaced apart from the sample distribution matrix, and to transfer the device to a test position, whereby the HDL test pad and reagent pad are in contact with the matrix. The claims of US

Patent no. 6,881,581 fail to teach that the HDL test pad and reagent pad are bonded together with either a heat formed bond or an acrylic acid copolymer adhesive bond. However, it would have been obvious to one of ordinary skill in the art to use a conventional type of bond, such as a heat formed bond or an acrylic acid copolymer bond, to adhere the HDL test pad and reagent pad in the method and device recited in the claims of US Patent no. 6,881,581, since the claims of US Patent no. 6,881,581 recite that the HDL test pad and reagent pad are laminated together, and laminates are known to be composed of multiple layers of material bonded together with a conventional type of bond such as a heat formed bond or an acrylic acid copolymer bond.

3. Claims 1, 4-14, 23-24, 29-30 and 32-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-10, 12-14, 17-21 and 24-25 of copending Application No. 10/410,671 (corresponding to publication no. US 2003/0224471). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite an assay device for measuring serum cholesterol associated with high density lipoproteins (HDL) in a blood fluid sample also containing lipoproteins other than HDL such as low density lipoprotein (LDL) and very low density lipoprotein (VLDL) comprising a sample distribution matrix effective to distribute a blood fluid sample from a sample application region to one or more sample collection regions, a HDL test pad in which HDL concentration can be assayed spaced apart from the sample distribution matrix, a reagent pad containing a reagent to selectively bind and remove non-HDLs from the sample, wherein the HDL test pad and reagent pad are joined together or attached to one another, and a mounting means that is effective to maintain the device in a sample distribution position, wherein the HDL test pad and reagent pad are spaced apart from the sample

distribution matrix, and to transfer the device to a test position, whereby the HDL test pad and reagent pad are in contact with the matrix. The claims of US Publication no. 2003/0224471 fail to teach that the HDL test pad and reagent pad are bonded together with either a heat formed bond or an acrylic acid copolymer adhesive bond. However, it would have been obvious to one of ordinary skill in the art to use a conventional type of bond, such as a heat formed bond or an acrylic acid copolymer bond, to adhere the HDL test pad and reagent pad in the method and device recited in the claims of US Publication no. 2003/0224471, since the claims of US Publication no. 2003/0224471 recite that the HDL test pad and reagent pad are laminated together, and laminates are known to be composed of multiple layers of material bonded together with a conventional type of bond such as a heat formed bond or an acrylic acid copolymer bond.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 23 and 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Anaokar et al (US 2003/0175153, submitted in the Information Disclosure Statement filed on November 29, 2005).

Anaokar et al teach of a device and method for determining HDL cholesterol in whole blood or plasma. The method comprises the steps of applying a blood sample to a device that comprises a test strip 20 having multiple layers therein. The top layer 36 is a spreader layer that serves as a sample reservoir and provides rapid and even disbursement of a body fluid. Below layer 36 is layer 38 that separates out red blood cells from the blood sample. Beneath layer 38 is layer 40, which is a porous layer that serves to separate out non-HDLs from the sample. Layer 40 is impregnated with a precipitating agent for precipitating out non-HDLs such as a polyanion in combination with a bivalent cation. The precipitating agent includes combinations of heparin and manganese chloride, dextran sulphate and magnesium chloride, or phosphotungstic acid and magnesium chloride. Since these are the same materials that are used in the instant invention for selectively binding to and removing non-HDLs from a fluid sample, the method and device taught by Anaokar et al includes passing a fluid sample through a reagent pad containing a reagent effective to selectively bind and remove non-HDLs from a fluid sample. A blood sample vertically flows through the layers of the device taught by Anaokar et al by gravity/capillary action. Non-HDLs are precipitated and retained in layer 40, while HDLs pass through to layer 42. In reaction layer 42, HDL reacts with an indicator to produce a colored, visual response. See Figure 1 and paragraph nos. 00610065, 0076-0078, and 0082 in Anaokar et al.

6. Claims 23 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Rittersdorf et al (US Patent no. 5,426,030, submitted in the IDS filed on November 29, 2005).

Rittersdorf et al teach of a method and device for the determination of HDL cholesterol. The method comprises applying a blood sample to a multi-layered device 1 depicted in Figure 1 of Rittersdorf et al. A blood sample is applied to layer 3, which travels through the different

layers by capillary forces. In layer 3, cellular blood components are separated out. The sample then travels to layer 4, which contains a precipitating agent therein for precipitating and separating out non-HDLs from the sample. Rittersdorf et al teach that the precipitating agent can be a combination of phosphotungstic acid and magnesium chloride, heparin and manganese chloride or dextran sulphate and magnesium chloride. Since these are the same materials that are used in the instant invention for selectively binding to and removing non-HDLs from a fluid sample, the method and device taught by Rittersdorf et al includes passing a fluid sample through a reagent pad containing a reagent effective to selectively bind and remove non-HDLs from a fluid sample. The sample then travels by capillary action to a fibre mesh layer 5 that serves to separate the lipoprotein precipitates formed in layer 4, and then to a test film 6 that contains a reagent to react with HDL cholesterol to form a visual colored response. See Figure 1, lines 56-68 in column 2, lines 1-30 in column 3, and lines 16-55 in column 4 of Rittersdorf et al.

7. Claims 23 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kozak et al (US Patent no. 5,460,974, submitted in the IDS filed on November 29, 2005).

Kozak et al teach of a method for assaying whole blood for HDL cholesterol. The method comprises applying a blood sample to a dry phase test strip device, as depicted in Figure 4 of Kozak et al. The blood sample travels through the laminar array of stacked pads in the device by gravity/capillary forces. The blood sample first contacts layer 90, which contains therein a separating reagent to remove the cellular components of the blood sample. The blood sample then travels to layer 88, which contains a precipitating reagent therein for precipitating and removing LDL and VLDL from the serum or plasma. The precipitating reagent can include reagents such as dextran sulfate, polyvinyl sulfate and phosphotungstic acid. Since these are the

same materials that are used in the instant invention for selectively binding to and removing non-HDLs from a fluid sample, the method and device taught by Kozak et al includes passing a fluid sample through a reagent pad containing a reagent effective to selectively bind and remove non-HDLs from a fluid sample. The fluid sample containing HDL then travels to optional filter layer 86 and then to test pad 84, which contains therein a reagent to react with HDL cholesterol to produce a visual, detectable response. See Figure 4, lines 23-40 in column 21, lines 7-34 in column 22, line 67 in column 23 and lines 1-41 in column 24 of Kozak et al.

8. Claims 23 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Thakore (US Patent no. 5,135,716, submitted in the IDS filed on November 29, 2005).

Thakore teaches of a method and device for the direct measurement of HDL cholesterol via a dry chemistry strip. The method comprises applying a blood sample to a device 10 that contains therein multiple stacked layers. Blood is added to a blood application area 11 of a physical transport medium 3. It travels along channels 2 to the layer 3. The blood then travels to layer 4, which contains therein reagents for separating the cellular components of blood as well as reagents for precipitating LDL and VLDL from the sample. Thakore teaches that the LDL and VLDL precipitating reagent can be dextran sulfate, heparin-manganese chloride or phosphotungstic acid in combination with magnesium chloride. Since these are the same materials that are used in the instant invention for selectively binding to and removing non-HDLs from a fluid sample, the method and device taught by Thakore includes passing a fluid sample through a reagent pad containing a reagent effective to selectively bind and remove non-HDLs from a fluid sample. The sample then passes through a filtering membrane 5 that filters off the LDL and VLDL precipitates and prevents them from reaching the plasma collecting test

membrane 6. The test membrane 6 contains reagents therein for reacting with HDL cholesterol to produce a detectable response. The blood sample travels through the multiple layers of the device by capillary action. See Figure 1, lines 1-64 in column 4 and lines 20-44 in column 5 of Thakore.

9. Claims 15-22, 31 and 34-37 are allowable over the prior art of record since none of this prior art of record teaches or fairly suggests a method for preparing a device suitable for measuring serum cholesterol that comprises providing a reagent pad either coated with an acrylic acid copolymer or formed of an asymmetric polysulfone membrane having a small pore side and an open pore side and containing a reagent effective to selectively bind and remove non-HDLs from a fluid sample, applying a HDL test pad containing HDL test reagents therein to the reagent pad, and heating to adhere the reagent pad and the HDL test pad together.

10. Applicant's arguments filed November 29, 2005 have been fully considered but they are not persuasive.

The previous rejections of the claims made in the last Office action mailed on August 29, 2005 under 35 USC 102(b) as being anticipated by Jones et al (US 2003/0224471) and Jones et al (US Patent no. 6,881,581) have been withdrawn in view of Applicant's amendments to the claims. The previous rejections of the claims under the judicially created doctrine of obviousness-type double patenting are maintained since Applicant has not filed appropriate terminal disclaimers in order to obviate these rejections. New rejections of some of the pending claims are set forth herein using prior art submitted in the Information Disclosure Statement (IDS) filed on November 29, 2005. Some of the references on this IDS have been crossed out

since these references were already considered and made of record on the IDS dated September 21, 2004 or the PTO-892 form attached to the Office action mailed on March 14, 2005.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

December 27, 2005

Maureen M. Wallenhorst
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